

REMARKS

Claims 1-15, 23, 28-30, 40-42, 75, and 76 are pending in the instant application. Claims 1-5, 23, 28-30, 40-42, 75, and 76 are withdrawn without prejudice for being directed to a non-elected invention. Claims 6-15 are currently under examination. Claims 6, 11, 12, and 14 are amended herein. Support for the amendments can be found throughout the application, for example in the claims as filed. Claims 7-9 have been cancelled without prejudice. After entry of the amendment, claims 6, and 10-15 will be pending.

The specification has been amended to make reference to the sequences now provided in the Sequence Listing. All sequences in the Sequence Listing were provided in the specification as filed. The Listing does not constitute new matter. Moreover, the amendment to the specification includes no new matter as the SEQ ID NOs inserted simply point to another section of the specification. Other amendments to the specification are to correct obvious typographical errors and do not include new matter.

Claim Objections

The Office Action has objected to claim 8 for the recitation of non-elected subject matter. Claim 8 has been cancelled obviating the rejection.

Objection to the Specification-- Sequence Compliance

The Office Action has objected to the specification for disclosing sequences that were not provided in a sequence listing. Applicant has amended the specification as set forth above and further provides herewith a sequence listing to comply with the requirements of 37 C.F.R. §1.821. Withdrawal of the objection is respectfully requested.

Rejection of Claims under 35 U.S.C. §112, Second Paragraph for Indefiniteness

The Office Action has rejected claims 6-15 for being indefinite for failing to particularly point out and distinctly claim the subject matter.

The Office Action asserts that claims 6-10 and 13 are unclear for not stating how the method steps accomplish the purpose of the claimed method. A similar rejection was made of claims 14 and 15. Further, the Office Action asserts that claims 6-13 and 14-15 are unclear for not setting forth any standard to which the nucleotide of P1 or P2 should be compared, and that claims 7 and 8 are unclear for not setting forth a standard for comparison of the nucleotide difference of KRAS2. Claim 8 is alleged to be unclear for recitation of a requirement of a nucleotide difference is G35A.

Further, the Office Action asserts that claims 11 and 12 are unclear for the recitation of “wherein a mutation level” without proper antecedent basis.

Applicant respectfully disagrees. However, to progress the prosecution of the application, claims have been amended as set forth above to more clearly set forth the matter Applicant intends to claim. Withdrawal of the rejections is respectfully requested.

Rejection of Claims under 35 U.S.C. §112, First Paragraph for Lack of Enablement

The Office Action has rejected claims 6-13 under 35 U.S.C. §112, first paragraph for not being enabled for the scope of the claims. However, the Office Action states that the specification is enabling for a method of differentiating pancreatic cancer from chronic pancreatitis in a subject by detecting a mutation encoding a G35A amino acid substitution in KRAS in a nucleic acid from a biological sample from the human subject using a ligation and amplification method wherein the presence of a mutation that encodes a G35A mutation is indicative of pancreatic cancer.

Without agreeing with the Examiner and purely to progress the prosecution of the application, Applicant has amended claim 6 as set forth above to recite the method for detection of a nucleic acid mutation encoding a G35A amino acid substitution in KRAS for the diagnosis of pancreatic cancer. As the remaining pending claims in the rejection, claims 10-13, are dependent on claim 6 and include all of the limitations of claim 6, they are also enabled by the specification. Withdrawal of the rejection is respectfully requested.

Rejection of Claims under 35 U.S.C. §102(b) for Anticipation

The Office Action has rejected claims 6, 9, 14, and 15 for allegedly being anticipated by Schouten et al (2002). Applicant respectfully disagrees.

However, to progress the prosecution of the application, Applicant has amended claim 6 to include the limitations of claims 7 and 8 which are not included in the rejection, overcoming the rejection of claim 6. Further, Applicant has cancelled claims 9, 14 and 15 without prejudice, overcoming the rejection. Withdrawal of the rejection is respectfully requested.

Rejection of Claims under 35 U.S.C. §103(a) for Obviousness

The Office Action has rejected claims 7, 8, and 10-13 under 35 U.S.C. §103(a) for being unpatentable over Schouten et al (2002) in view of Marie et al. (2002) and Lecomte (2002). Applicant respectfully disagrees. However, to progress the prosecution of the application, Applicant has amended claim 6 to include all of the limitations of claim 9 which is not included in the rejection. Further, claims 10-13 are dependent on the now allowable claim 6, overcoming the rejection. Withdrawal of the rejection is respectfully requested.

CONCLUSIONS

In view of the above amendments and remarks, Applicants believe the pending application is in condition for immediate allowance. However, if the Examiner believes that there are any outstanding issues in the case that could be addressed by telephone conference, the Examiner is encouraged to contact the Agent for Applicant listed below to discuss the matter.

PETITION AND FEE AUTHORIZATION

The Commissioner is hereby authorized to charge the fee for one month extension of time for reply, small entity in conjunction with this response. No further fees are believed to be due. The Commissioner is authorized to charge any fees

associated with this submission to our Deposit Account, No. 04-1105, Reference 65370(71526). Any overpayment should be credited to said Deposit Account.

Dated: March 23, 2009

Respectfully submitted,

Electronic signature: /Colleen McKiernan/
Colleen McKiernan, Ph.D..

Registration No.: 48,570

EDWARDS ANGELL PALMER & DODGE
LLP

P.O. Box 55874

Boston, Massachusetts 02205

(617) 517-5555

Attorneys/Agents For Applicant